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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,690	03/07/2002	Hubert H. Girault	JYG149USA	8826
270	7590	03/22/2006		
HOWSON AND HOWSON SUITE 210 501 OFFICE CENTER DRIVE FT WASHINGTON, PA 19034			EXAMINER SINES, BRIAN J	
			ART UNIT 1743	PAPER NUMBER

DATE MAILED: 03/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)
	09/937,690	GIRAUT ET AL.
	Examiner	Art Unit
	Brian J. Sines	1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 03 January 2006.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,2,9,10,15,16,19,22,23,25-29,31,33,36,38,41,42,44,46,54,58,60-89 and 92-96 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ . |

Continuation of Disposition of Claims: Claims pending in the application are 1,2,9,10,15,16,19,22,23,25-29,31,33,36,38,41,42,44,46,54,58,60-89 and 92-96.

DETAILED ACTION***Claim Rejections - 35 USC § 102***

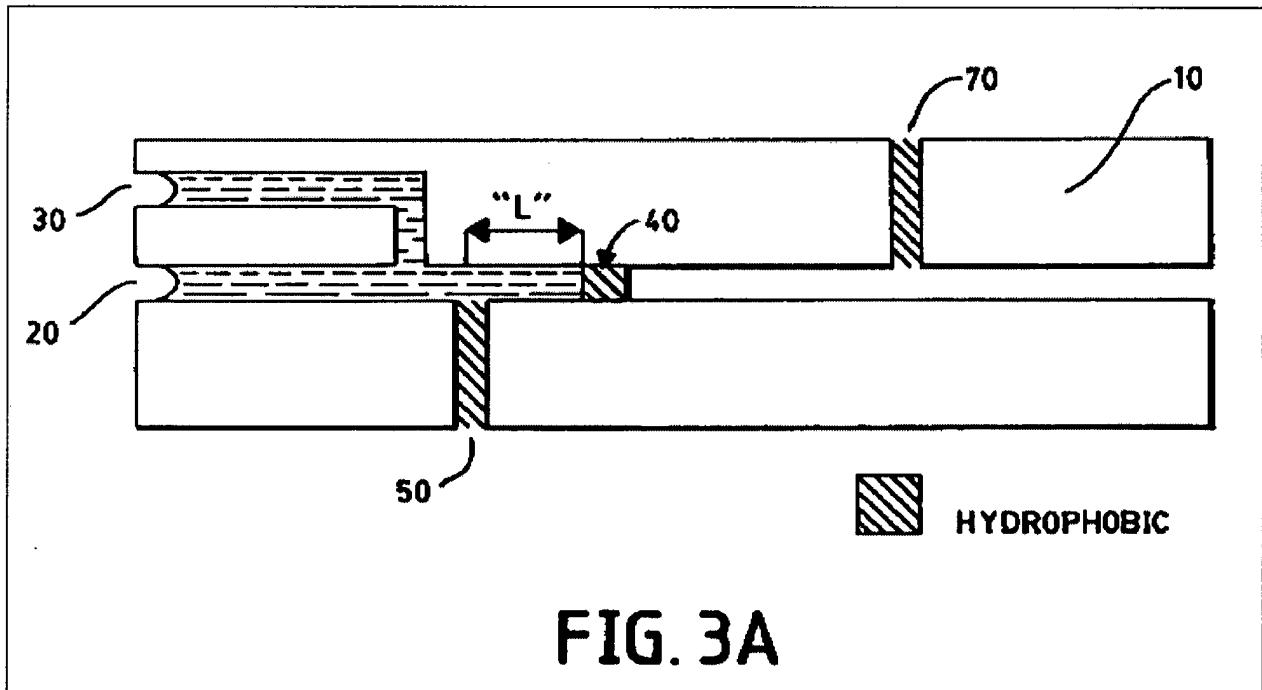
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1 & 2, 9, 10 are rejected under 35 U.S.C. 102(e) as being anticipated by Handique et al. (U.S. Pat. No. 6,130,098 A) (hereinafter “Handique”).

Regarding claim 1, Handique teaches an apparatus comprising: a chamber (e.g., the region to the right of hydrophobic region 40) having an inflow channel (20), wherein the channel comprises a hydrophobic region (40) (see col. 14, lines 24 – 64; figure 3A).



Regarding claim 2, Handique teaches microchannel dimensions of between 0.5 µm to 50 µm in depth (see col. 7, lines 44 – 63).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 9, 10, 60 – 63 & 65 – 71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Handique.

Regarding claims 10 & 60 – 62, Handique teaches an apparatus comprising: a chamber (e.g., the region to the right of hydrophobic region 40) having an inflow channel (20), wherein the channel comprises a hydrophobic region (40) (see col. 14, lines 24 – 64; figure 3A).

Regarding claim 9, Handique teaches the incorporation of additional separate channels (e.g., 30, 50 or 70) (see col. 14, lines 24 – 57; figure 3A).

Claim 65 is considered a process or intended use limitation. The Courts have held that a statement of intended use in an apparatus claim fails to distinguish over a prior art apparatus. See *In re Sinex*, 309 F.2d 488, 492, 135 USPQ 302, 305 (CCPA 1962).

Regarding claim 66, Handique does not specifically teach the incorporation of a plurality of separate reaction chambers or channels. The Courts have held that the mere duplication of parts, without any new or unexpected results, is within the ambit of one of ordinary skill in the art. See *In re Harza*, 124 USPQ 378 (CCPA 1960) (see MPEP § 2144.04). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate a plurality of chambers or channels as recited in claim 66.

Regarding claims 67 – 71, Handique teaches various microchannel dimensions, e.g., a microchannel depth of between 0.5 µm to 50 µm (see col. 7, lines 44 – 63). As shown in figure 3A, Handique teaches that the various channels can be arranged either parallel to each other or perpendicular to a common conduit comprising hydrophobic region 40.

2. Claims 16, 19, 22, 23, 25 – 29, 31, 36, 38, 41, 42, 44, 46, 64, 72 – 89 & 92 – 96 are rejected under 35 U.S.C. 103(a) as being unpatentable over Handique, as applied to claims 9, 10, 60 – 63 & 65 – 71 above, and further in view of Mian et al. (U.S. Pat. No. 6,709,869 B2) (hereinafter “Mian”).

Regarding claims 16, 22, 19, 72 – 77, Handique does not specifically teach the use of a radial or circular substrate configuration for the analytical microfluidic apparatus. Mian teaches a radially-configured analytical microfluidic apparatus, which relies on centripetal forces to facilitate sample transport and processing. The disclosed apparatus comprises various sample fluid inlet ports, microchannels, chambers/cavities, valves, heating/cooling elements,

electrophoretic elements and detection systems upon a single disk for sample processing and analysis (see col. 3, line 25 – col. 4, line 42; col. 26, lines 8 – 48). Mian teaches various pertinent apparatus structural dimensions (see col. 8, lines 14 – 50). As indicated by Mian, a person of ordinary skill in the art would have recognized the suitability of utilizing a radially-configured analytical microfluidic apparatus. Hence, as evidenced by Mian, a person of ordinary skill in the art would accordingly have had a reasonable expectation for success in utilizing a radial configuration for the disclosed apparatus. The Courts have held that the prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success. See *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986) (see MPEP § 2143.02). Therefore, it would have been obvious to a person of ordinary skill in the art in utilizing a radial configuration for the disclosed apparatus.

Regarding claim 23, Mian teaches the incorporation of pneumatically-actuated membrane valves, which incorporate the use of a plunger or piston, and single-use valve structures (see col. 18, line 35 – col. 19, line 67). The use of single-use valves comprising breakable seals are well known in the art. Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate such a valve system with the disclosed apparatus in order to facilitate effective sample fluid transfer.

Regarding claims 25 – 29, 31, 46, 78 & 79, Mian teaches the incorporation of a fluorescent, chemiluminescent and electrochemical detection means, which are well known in the art (see col. 7, lines 56 – 65; col. 21, line 29 – col. 24, line 37; col. 26, line 52 – col. 27, line 25).

Regarding claim 64, Mian teaches the use of pipettes for facilitating fluid transfer with the disclosed microfluidic apparatus (see col. 26, lines 8 – 48). Mian specifically teaches that the pipette tips fit into the access ports on the surface of the apparatus (see col. 26, lines 17 – 21). Therefore, it would have been obvious to a person of ordinary skill in the art to provide a molded inflow port or channel with the disclosed apparatus in order to facilitate effective sample fluid transfer.

Regarding claim 80, Mian teaches the incorporation of photomultiplier tubes (see col. 37, lines 48 – 63).

Regarding claims 33, 36, 38, 81 – 85, Mian teaches the incorporation of immobilized chemical reagents, such as antibodies, for sample analysis and processing (see col. 35, line 61 – col. 37, line 47).

Regarding claim 86, Mian teaches surface modification (see col. 14, lines 42 – 67).

Regarding claims 41 & 87, these claims are considered a product-by-process claims. The patentability of a product or apparatus does not depend on its method of production or formation. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. See *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (see MPEP § 2113).

Regarding claims 41, 42 & 88, Mian teaches that the substrate is made from various elastomeric polymer materials (see col. 14, lines 1 – 41).

Regarding claim 44, the use of polydimethylsiloxane (PDMS) as a fabrication material for microfluidic devices is well known in the art. Therefore, it would have been obvious to a

person of ordinary skill in the art to incorporate the use of PDMS as a fabrication material for the disclosed microfluidic apparatus.

Regarding claim 89, Mian teaches the use of an electromagnetic radiation detection means (see col. 22, line 1 – col. 23, line 28).

Regarding claims 54, 58, 92 – 96, Mian and Handique teaches all of the structure of the apparatus provided in the claimed method, which merely recites the conventional operation of that apparatus. Therefore, it would have been obvious to a person of ordinary skill in the art to perform the method recited in the instant claims, as such is the intended operation of that apparatus.

Response to Arguments

Regarding the rejection of claims 1 & 2, 9, 10 under 35 U.S.C. 102(e) as being anticipated by Handique, Applicant's arguments filed 1/3/2006 have been fully considered but they are not persuasive. The applicant essentially argues that Handique fails to teach an inflow channel that prevents any entry of aqueous fluid into the apparatus and microchannel until fluid entry force is applied to permit fluid flow through the fluid inflow channel. However, the instant claims are drawn to an apparatus statutory class of invention. Handique teaches all of the positively recited structure of the claimed apparatus. It is the structural limitations of the apparatus, as recited in the claims, which are considered in determining the patentability of the apparatus. These claims recite various process or use limitations and are accorded no patentable weight to an apparatus. For example, these claims recite how the apparatus is to be operated, which does not impart any further limitations to define the structure of the apparatus being claimed from the prior art. Process limitations do not add patentability to a structure, which is

not distinguished from the prior art. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967); and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). The Courts have held that it is well settled that the recitation of a new intended use, for an old product, does not make a claim to that old product patentable. See *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997). The Courts have held that apparatus claims must be structurally distinguishable from the prior art in terms of structure, not function. See *In re Danley*, 120 USPQ 528, 531 (CCPA 1959); and *Hewlett-Packard Co. V. Bausch and Lomb, Inc.*, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). The Courts have held that the manner of operating an apparatus does not differentiate an apparatus claim from the prior art, if the prior art apparatus teaches all of the structural limitations of the claim. See *Ex Parte Masham*, 2 USPQ2d 1647 (BPAI 1987) (see MPEP § 2114).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Sines, whose telephone number is (571) 272-1263. The examiner can normally be reached on Monday - Friday (11 AM - 8 PM EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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